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# **The effects of providing periodontal disease risk information on psychological outcomes- a randomized controlled trial**

*Running title: Risk communication & behavioural outcome*

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## **Conflicts of Interest**

The authors report no conflicts of interest.

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## Abstract

**Aim:** In a two arm randomised controlled trial this study compared the effects of a routine periodontal assessment consultation vs. a routine consultation + individualised risk assessment communication intervention on patient thoughts and emotions about periodontal disease.

**Materials and Methods:** Adults (N=102) with moderate/advanced chronic periodontitis referred to a Periodontology Department of a large UK dental school, completed psychological measures before a periodontal assessment and again at the end of the visit. Intervention participants received an individualised calculation of their periodontal disease risk using PreViser Risk Calculator in addition to their routine assessment consultation.

**Results:** In routine care, patients' thoughts about periodontal disease seriousness ( $p<0.001$ ) and susceptibility ( $p<0.03$ ) increased post-consultation and participants felt more positive ( $p<0.02$ ) about periodontal disease. These effects were also seen in intervention participants. Additionally, the individualised risk communication intervention led to patients reporting i) periodontal disease treatment as more effective than they did pre-consultation ( $p<0.001$ ), ii) feeling more confident in their ability to adhere to treatment as seen in increases in self-efficacy ( $p<0.05$ ) and iii) higher intentions to adhere to periodontal management ( $p<0.03$ ).

**Conclusions:** Individualised periodontal disease risk communication influences psychological variables that underpin adherence with periodontal instructions.

## Clinical relevance

**Rationale:** Patient adherence with periodontal instructions is influenced by thoughts/feelings. The effect of a routine periodontal assessment on how patients think and feel about periodontal disease management was explored. Whether giving patients personalised risk of periodontal disease affects thoughts and feelings differently to routine care was also examined.

**Principal Findings:** Patients thought and felt differently about periodontal disease after a routine consultation. Individualised risk information prepared patients better to adhere to dental instructions than a routine consultation.

**Practical Implications:** Patients' preparedness to adhere to periodontal instructions was affected by the type of information they receive at assessment.

## Background

The control of periodontal disease requires a partnership between the dental team and the patient. While the dental team can remove the threat or ameliorate the more severe manifestations of the disease by removal of local causative factors, long-term maintenance of periodontal health requires the patient to effectively undertake a range of oral hygiene behaviours (Rosling, 1983, Westfelt et al., 1998, Nyman et al., 1975). Effective toothbrushing, for example, depends on a person's motivation, knowledge and manual dexterity (Deacon et al., 2010). Whilst knowledge and manual dexterity may be addressed in the dental surgery fairly easily, supporting patients' motivation to adhere with oral health instructions can be less straightforward (Asimakopoulou and Daly, 2009, Renz and Newton, 2009, Asimakopoulou and Newton, 2014).

The role of the behavioural sciences in helping patients improve adherence in oral health settings has been examined previously (Renz et al., 2007, Renz and Newton, 2009). Several health behaviour models that may support adherence with periodontal instructions have been reviewed and the predictive power of each evaluated (Asimakopoulou and Daly, 2009, Renz and Newton, 2009). Within these models a central idea is that patients' future oral health behaviour may be affected by how much patients perceive they are at risk of further oral health disease.

In medicine the results of numerous health risk communication studies have led to the recommendation that *personalised* risk communication may be helpful in supporting patients' adherence with health advice (Edwards et al., 2013). In dental settings on the other hand, although it has been suggested that individualised risk estimates (Garcia et al., 2009) and biofeedback (Barnfather et al., 2005) may be potentially helpful in supporting behaviour change there is a dearth of empirical evidence exploring the role of individualised risk communication on oral health behaviours. Thus, although dental practitioners believe that discussion of personalised oral health risk estimates might generally help improve dentist-patient communication (Busby et al., 2013), the effects of such communication on patients are not known.

Studies in medicine have suggested that risk perception is "*primarily determined not by facts but by emotions*" (Paling, 2003). Emotional reactions to one's risk of illness development are important as they may be related to motivation to engage in illness-preventive behaviours. For example, fear may help increase people's motivation to engage in health-protective behaviours (Tanner et al., 1991). On the other hand, too much fear may lead people to ignore (Brown, 2001) or fail to recall (Reed and Aspinwall, 1998, Lench and Levine, 2005) risk information. The extent to which the communication of risk information will lead to fear is thus important.

Psychological models such as Protection Motivation Theory (Rogers, 1983) can provide a framework to predict whether patients will take up a risk-reducing behaviour as a result of being told that they are at risk of further disease. The theory proposes that patients' motivation to engage with health protective behaviour will be a function of:

- (i) Thoughts about disease seriousness and their susceptibility to it (with high susceptibility and seriousness beliefs leading to feeling fearful) and
- (ii) Thoughts about their ability to perform the behaviours required to control the illness (self-efficacy) and the perceived barriers to health-protecting behaviours (contributing to beliefs about coping with the illness).

For health-protective behaviour to take place eliciting fear of the illness is not enough; instead, people need to also perceive that they have the tools necessary to cope with it (Witte and Allen, 2000).

In periodontal settings central to the development of treatment plans is a routine assessment by the consulting clinician of the risk for future periodontal disease and the communication of the assessment findings to patients. It is unclear, however, what the impact of such a routine periodontal consultation might be on patients' thoughts and feelings about periodontal disease and hence their motivation to take up health protecting behaviours.

In line with the psychological model described above, best practice on risk communication in medical settings (Edwards et al., 2013) and current evidence regarding risk communication in dental settings (Busby et al., 2013), suggests one way to support patients with adhering to periodontal treatment instructions might be to educate them about their *individual* susceptibility to further disease. In doing so, it is necessary to know what the effects of individualised risk communication of periodontal disease are on patients' thoughts and emotions and whether these effects are different from the effects of a routine periodontal consultation.

The purpose of this study is thus three-fold. Its aims are to examine:-

1. The effect of a *routine* periodontal assessment consultation on patients' cognitions and emotions surrounding periodontal treatment;
2. The effect of an *individualised periodontal risk* consultation on patients' cognitions and emotions surrounding periodontal treatment;
3. The extent to which *individualised* periodontal risk information has a stronger impact than *routine* periodontal assessment communication on patients' cognitions and emotions.

## Materials and methods

This was a single-blind, two arm randomised controlled trial where the effects of a routine assessment consultation (Control) vs. a routine + individualised risk communication intervention on patient thoughts and emotions were compared. All patients were assessed on psychosocial variables before a routine assessment consultation and then again at the end of the visit. Control participants received a routine periodontal assessment consultation followed with general questions and answers about oral health with a researcher (YK). Intervention patients received individualised periodontal risk information by the researcher, following their routine consultation. Patients were randomly allocated to arms using a random digit generator. The study was approved by a NHS Research Ethics Committee (Ref: 12/LO/0698).

New adult referrals to a Periodontology clinic at the Dental Institute King's College London, who presented with moderate to advanced chronic periodontitis between September 2012 and July 2013 were eligible to participate. Potential participants were approached and recruited by a researcher whilst waiting for their routine appointment. The study purpose was explained and full written consent was obtained. A financial incentive to participate was not offered.

Patients who agreed to participate were screened for eligibility. Firstly, patients' ability to speak English was noted. Fluent English speakers were then excluded if they were current smokers (smoking within prior 30 days), had any medical condition that was likely to affect their periodontal status (e.g. diabetes, drug-associated gingival overgrowth, pregnancy, reported psychiatric co-morbidity), had any physical impairment that might impact on their ability to clean their teeth, were currently using chlorhexidine mouthwash, had been taking antibiotics or had received any periodontal treatment during the previous three months. Patients who during their periodontal assessment were diagnosed with a condition that did not constitute periodontal disease (e.g. lichen planus) were subsequently excluded from the study.

Those patients who remained eligible were invited to complete a battery of psychological measures. These were:

1. The Positive Affect Negative Affect Scale (PANAS) (Watson et al., 1988) This is a reliable and valid Likert scale-based measure, which evaluated patients' emotional reactions to their periodontal assessment by providing a score for a series of positive (e.g. feeling excited, interested, attentive) and negative (e.g. feeling distressed, upset, scared) emotions. The measure yields two scores, a positive emotion score and a negative emotion score. In both cases the higher the score the stronger the particular emotion was experienced.
2. A Protection Motivation Theory (PMT) questionnaire was devised following standard guidance (Conner and Norman, 2005). This seven-item Likert scale questionnaire (ranging from 1: *Not at all* to 10: *Extremely so*) examined beliefs about periodontal disease along the dimensions of disease seriousness (i.e. *Periodontal disease is a serious illness*), susceptibility (i.e. *If left untreated my chances of developing periodontal disease in the future are high*), treatment effectiveness (i.e. *Adhering to my periodontal treatment instructions over the next 8-12 weeks will improve my oral health*), self-efficacy (i.e. *I am confident I can follow my periodontal treatment instructions over then next 8-12-weeks*), treatment cost/barriers (i.e. *Adhering to my periodontal treatment instructions over the next 8-12 weeks will be hard to remember / difficult to do*), fear (i.e. *Periodontal disease worries me*) and intention to adhere to treatment instructions (i.e. *I intend to follow through my periodontal treatment plan over the next 8-12 weeks*).
3. The Hospital Anxiety and Depression Scale (HADS-A/D) (Zigmond and Snaith, 1983) was used to screen out patients with clinical anxiety / depression. This is a standard, widely used screening tool for anxiety (7 items; e.g. *I feel tense or wound up*; *Worrying thoughts go through my mind*)

and depression (7 items; e.g. *I can laugh and see the funny side of things; I feel cheerful*) scored on a scale from 0 – 3 (e.g. *0: Not at all – 3: Most of the time*). Total scores of 11+ for either depression or anxiety indicate the presence of a clinical disorder.

Following pre-consultation questionnaire completion, patients were randomly allocated to either intervention or control condition. Both groups underwent their routine clinical assessment, including oral examination and 6 point probing depth and bleeding assessment followed by radiographs or other investigations where indicated. Following the clinical examination all participants met with the researcher again. Participants in the intervention group spent 5-10 minutes going through an individualised calculation of their periodontal disease risk using PreViser Risk Calculator, version 3.1.0 ([www.previser.com](http://www.previser.com)). This software is an online tool which can be used to provide an objective analysis of a patient's oral disease risk and severity in the form of colour coded charts: risk is reported on a scale of 1 (very low risk) to 5 (very high risk), and disease severity on a scale from 1 (healthy) to 100 (severe periodontitis) (Page et al., 2002, Page et al., 2003, Garcia et al., 2009). A standard script explaining the risk information provided by Previser was developed and followed throughout. Specifically, the researcher went through the standard Previser output with the patient, explaining, in general terms the idea of risk and referring to some factors such smoking that might adversely impact one's risk score. She then moved on to explain the patient's specific risk profile and where their risk sat in the 1- 5 scale, with reference to lifestyle and oral health factors that might impact those scores. Following this, she moved on to explaining their current periodontal disease scores and what the numbers meant, again in relation to the 1- 100 scale. She then explored patient reactions to these scores and ways the patient felt they might follow periodontal treatment advice. Control group participants engaged in a question and answer session about general oral health for the same amount of time but at no time was risk of disease discussed with them. At the end of this researcher-led session, all participants completed the PMT and PANAS measures again.

### *Statistical Methods*

Per protocol analysis of data that violated parametric test assumptions, was undertaken; non-parametric two group tests were performed comparing scores within (pre –post consultation; Wilcoxon paired samples test) and across groups (intervention – control; Mann-Whitney U test). Cronbach's alpha was calculated for the PMT scale overall in order to assess internal consistency.

## Results

Of the 174 patients approached 150 fulfilled eligibility criteria in terms of reason for referral and age. Of those, 102 patients remained eligible and happy to participate following screening. A total of 81 participants (38 in the intervention group) provided full psychosocial data pre and post consultation.

Figure 1 shows a CONSORT flow chart for this RCT.

---- Figure 1 about here -----

The sample's mean age was 46.10 (SD=10.83) years and there were more females (N=49) than males (N=30) with two participants not disclosing their gender. One participant with a score indicative of clinical depression on the HADS was excluded from any further analyses. The sample's overall general anxiety (HADS-A M=7.56, SD=4.27) and depression (HADS-D M=3.49, SD=3.00) scores were within normal levels.

Descriptive statistics (Table 1) were calculated for all psychological outcome variables, pre and post consultation, for the control and intervention groups separately. All analyses were carried out blind as to the identity of the two groups.

-----Table 1 about here -----

PANAS scores were arrived at through standard procedure. PANAS variables thus had a possible range of 10 – 50 with higher scores indicating a more positive (PANAS positive) or more negative (PANAS negative) mood. The PMT variables were scored on a 10-point Likert scale with higher scores indicating a higher level of the measured construct.

### *Randomization, reliability and power checks*

There were no significant differences between intervention and control participants pre-consultation in any of the measured variables (p. range 0.21 – 0.97) confirming the success of the randomization procedure.

The Protection Motivation Scale was assessed for reliability. Cronbach's alpha was  $\alpha=.654$ , improving to  $\alpha=.740$  if the treatment costs / barriers item was removed.

At the 95% confidence level and assuming a small effect of  $d=0.25$ , the obtained sample size of  $N=82$  gave the current study power of 80.7%.



### *Inferential statistical analyses*

1. What is the effect of a *routine* periodontal consultation on participants' cognitions and emotions surrounding periodontal disease?

Pre and post-consultation data for participants in the control arm were examined in order to assess the effects of the routine dental consultation on thoughts and emotions. Wilcoxon tests showed that post-consultation, participants thought that periodontal disease was more serious ( $Z=3.61$ ,  $p<.001$ ) than they thought it was before consultation and that they were more susceptible to it ( $Z=2.20$ ,  $p<.03$ ). The consultation had no other effects on any other thought constructs measured. Routine care participants felt more positive emotions ( $Z=2.37$ ,  $p<.02$ ) and fewer negative emotions ( $Z=2.42$ ,  $p<.02$ ) post-consultation than they did pre-consultation.

2. What is the effect of an *individualised periodontal risk* consultation on participants' cognitions and emotions surrounding periodontal treatment?

Pre and post-consultation data for participants in the intervention arm were evaluated. Post-consultation, participants who had had a discussion about their individualised periodontal disease risk score, thought that periodontal disease was more serious ( $Z=3.63$ ,  $p<.001$ ), that they were more susceptible to it ( $Z=2.26$ ,  $p<.02$ ) and that periodontal treatment would be more effective in controlling periodontal disease ( $Z=3.38$ ,  $p<.001$ ) than they thought pre-consultation. They also felt better able to follow through the dental advice they had received as seen in increases in self-efficacy ( $Z=2.02$ ,  $p<.05$ ). Individualised risk communication about periodontal disease had no other effects on any of the remaining thought constructs. Patients in the intervention group reported more positive emotions ( $Z=3.33$ ,  $p<.001$ ) post-consultation than before.

3. Does *individualised* periodontal risk information have a stronger impact than *routine* periodontal assessment on participants' cognitions and emotions?

Post-consultation psychological data from control and intervention groups were compared using Mann Whitney U tests. The intervention group's perceptions of seriousness of periodontal disease was higher post consultation than those of the control group ( $U=519.5$ ,  $p<.04$ ) as were their intentions to adhere to periodontal treatment ( $U=519.5$ ,  $p<.03$ ). There were no other differences post consultation between the routine care (control) and individualised risk communication (intervention) groups.

## Discussion

People with periodontal disease are often unaware that they have the disease. This study demonstrated that even in a routine clinical assessment, the dentist-patient encounter can increase awareness of periodontal disease in terms of individual susceptibility and seriousness and far from this being seen as scare mongering, patients feel positive about receiving this information. An individualised risk communication strategy also produced these effects, but, in addition, this personalised risk communication intervention also increased people's belief about periodontal treatment effectiveness as well as beliefs about their own ability to adhere to periodontal treatment instructions (self-efficacy). In addition, individualised risk communication enhanced people's self-reported intention to adhere to periodontal treatment more than a standard routine consultation. The time frame of the study was too short to allow us to assess whether the change in cognitions and emotions was translated into sustained long-term behaviour change, nevertheless these preliminary behavioural data are encouraging.

As oral health needs assessments are increasingly incorporating risk assessments for future disease, it is important that the best way to communicate this risk is understood. In the present study, there is a suggestion that individualised risk communication may increase motivation for behaviour change and may make patients more receptive to receiving information and to developing new skills in relation to oral hygiene. These findings are in line with work in relation to medical screening uptake, where studies suggest that individualised risk communication might be more effective when compared to generalised communication (Edwards et al., 2013).

These findings sit comfortably within recent developments in behaviour change science (Asimakopoulou and Newton, 2014). Here, it has been proposed that for behaviour (B) change to take place, healthcare professionals need to address people's Capability (C), Opportunity (O) and Motivation (M) (Michie et al., 2009, West and Michie, 2010). These data would suggest that both routine and individualised risk consultations may be successful at tackling the C and O components of this model, by for example, dental practitioners demonstrating effective tooth-brushing (Capability) and highlighting Opportunities for behaviour change. However, individualised risk communication seems better placed to also tackle people's motivation to adhere to periodontal instructions, as seen in improvements in self-efficacy, enhanced beliefs in periodontal treatment effectiveness and enhanced self-reported intention to adhere to periodontal treatment plans.

There are a number of limitations to this study, which must be acknowledged. Firstly, although the changes in psychological constructs described here point towards the importance of the behavioural sciences in assisting dental practitioners with behaviour change in the dental surgery, no data have been provided as to whether these behavioural effects get translated into behaviour change as measured by e.g. some objective clinical data. It is suggested that future work builds on the current findings and collects objective clinical data such as plaque, bleeding and pocket depth scores before and after an individualised risk communication intervention to ensure that the behavioural construct changes reported here truly support patient behaviour change.

Secondly, the holy grail of any behavioural intervention is to produce long-term sustainable improvements in behaviour (Watt and Marinho, 2005). In this sense, the time period for this study was short and future studies should look to collect objective clinical data at normal follow-up (8-12 weeks post intervention) but also at a longer data collection period of six to twelve months.

To conclude, both routine and individualised risk communication-based periodontal consultations impacted the way patients think and feel about periodontal disease and its treatment.

In routine care, thoughts about disease seriousness and susceptibility increased post-consultation and patients felt more positive about it. The same pattern of thought and emotion process change was seen following individualised risk communication, only in this case, patients also saw periodontal disease treatment as more effective than pre-consultation, they felt more confident in their own ability to follow a periodontal treatment regimen and reported higher intentions of adhering to periodontal disease instructions.

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### **Table and Figure legends**

Table 1: Mean, standard deviation (SD) and Confidence Intervals (CIs) for psychosocial outcome measures, pre and post treatment, per group.

Figure 1: CONSORT chart showing the flow of participants through the study